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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,363	08/14/2003	Jong-Wan Park	13100-02CIP	1639

7590 12/19/2006  
JHK Law  
P.O. Box 1078  
La Canada, CA 91012-1078

EXAMINER
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ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/642,363	<b>Applicant(s)</b> PARK ET AL.	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This office action is in response to the Amendment filed September 25, 2006. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claims*

#### **Claim Rejections - 35 USC § 112 – Lack of Enablement**

1) Claims 7-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of tumor growth with the mannose YC-1 derivative, does not reasonably provide enablement for inhibiting HIF-1  $\alpha$  expression in tumor cells or tissues, inhibiting tumor growth, inhibiting HIF-1-regulated gene expression, inhibiting angiogenesis in tumor cells or tissues, inhibiting tumor progression and metastasis treating a HIF-1- mediated disorder or condition by all polyol YC-1 derivatives claimed. The rejection is maintained.

Applicant argues it is the initial burden of the Examiner to set forth reasonable explanation as to why he/she believes that the scope of protection provided by the claim is not adequately enabled and further supports this with case law. The examiner has failed to establish why they believe that the presently claimed invention directed to the mannose YC-1 derivative for inhibiting expression of HIF-1  $\alpha$  in tumor cells is not enabled by the disclosure in the specification. In the absence of such evidence or scientific reasoning, Applicants submit that the present application must be considered

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enabling. Applicant further argues they have demonstrated that the YC-1 compound has HIF-1 $\alpha$  inhibiting activity. Therefore it expected that the mannose YC-1 derivative would have HIF-1  $\alpha$  inhibitory activity as well. In the absence of evidence to the contrary, the specification must be considered to be enabling for the claimed invention. The argument is not persuasive.

Applicant's arguments are not understood. The rejection is a scope of enablement rejection stating mannose YC-1 is enabled but not all of the polyol derivatives encompassed by the claims are enabled. Applicant argues that the rejection recites the mannose YC-1 derivative is not enable which is not the case. In order to support the claim as recited, examples disclosing a representative set of the polyol derivatives encompassed by the claims should be provided in the disclosure and not just one derivative. The Examiner supports this with the cited reference which discloses not all derivatives of YC-1 exhibits the same function as YC-1, therefore it cannot be assume just because one derivative exhibits like behavior as YC-1, that all the derivatives will exhibit the same behavior. Because Applicant has not shown support for the claims by providing examples with a representative number of polyol derivatives, the claims for all polyol derivatives is not enabled.

2) Claims 7-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of tumor growth with the mannose YC-1 derivative in hepatoma cells in a xenograft, does not reasonably provide enablement for inhibiting HIF-1 $\alpha$  expression in tumor cells or tissues, inhibiting tumor

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growth, inhibiting HIF-1-regulated gene expression, inhibiting angiogenesis in tumor cells or tissues, inhibiting tumor progression and metastasis treating a HIF-1- mediated disorder or condition for all cancers by all polyol YC-1 derivatives claimed.

Applicant argues that while experimentation was done with hepatoma cells, it is not unrealistic to expand the usage of mannose YC-1 derivative to other tumor types, with a reasonable expectation that the growth of other tumor types would be inhibited. Applicants should not be limited to the activity of mannose YC-1 on xenografts only. The mouse used in the experiments serves as a model animal for testing the efficacy of anti-tumor agents. Therefore, successful result in such xenografts as described in the present specification serves to provide an enabling disclosure for the claimed invention. This argument is not persuasive.

As disclosed by the cited references there is no one drug that can broadly treat cancer, therefore it is unpredictable that just because the mannose derivative works in hepatoma does not mean it works for all tumor cells. Applicant provides not evidence to contradict this statement by the cite reference and reasonable expectation is not strong enough to contradict the cited reference's findings. The cited reference Gura recites "the fundamental problem in drug discovery for cancer is that the model systems are not predictive" which casts reasonable doubt on any expectations of therapy beyond hepatomas. In regards to the xenograft, it cannot be predicted by this type of testing that angiogenesis can be inhibited as supported by the cited reference which discloses the potential shortcomings of potential anti-cancer agents including extrapolating from *in vitro* to *in vivo* protocols, the problems of drug testing in knockout mice, and problems

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associated with clonogenic assays.

3) Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of hepatoma with the mannose YC-1 derivative, does not reasonably provide enablement for the treatment of all HIF-1-mediated disorder or conditions in a mammal with all polyol YC-1 derivatives. The rejection is maintained.

It does not appear Applicant has addressed this rejection in regards to claim 19. Applicant argues other types of tumors but not other types of HIF-1-mediated disorders such as ischemic disorders. In regards to claims 20 where the disorders are tumor related, see Examiner's answer above.

#### **Claim Rejections - 35 USC § 112 - Indefiniteness**

Claims 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The claim uses the term "HIF-mediated" yet it does not specifically point out if the disorder is mediated positively or negatively. Interpreting the claims as is suggest the compound can affect the disorder both positive and negatively, which is highly unlikely. The claim does not define the metes and bound to which the invention applies. This rejection is maintained.

Applicant argues claims 19-20 are definite since mannose YC-1 derivative is effective for inhibiting a HIF-1 $\alpha$  activity, any disorder that is caused by HIF-1 $\alpha$

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expression would be treatable with the mannose YC-1 compound of the presently claimed invention.

The claims are indefinite insofar as it does not clearly recite the disorder is positively or negatively mediated.

Claims 7-20 are rejected.

No claims allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lezah Roberts  
Patent Examiner  
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Frederick Krass  
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